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EXAMINER	
MYERS, CARLA J	

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1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/647,982	Applicant(s) KAYTES ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-56* is/are pending in the application.

4a) Of the above claim(s) *31-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/15/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 30 and the particular set of polymorphisms at positions 601 and 1038 in the reply filed on October 2, 2006 is acknowledged.

The traversal is on the ground(s) that the claims do in fact recite a proper Markush group. It is stated that Applicants do not agree with the Examiner's "re-definition" of well established Markush practice. These arguments have been fully considered but are not found persuasive. Members of a Markush group are considered to be of a similar nature only when the compounds share a common property or activity and have a common structure essential to that property or activity (see MPEP 808.02: "Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility"). In the instant situation, while the haplotypes all comprise nucleotide sequences, the haplotypes do not share a common structure because each haplotype consists of a distinct nucleotide variation, which occurs at a distinct position in the sequence of SEQ ID NO: 1. Further, each of the individual polymorphisms and haplotypes comprising these polymorphisms are transmitted to affected and non-affected offspring at different frequencies, and are present in control populations at different frequencies, and thereby do not have the same activity and effect.

The response states that "the nucleotide sequences are not "compounds." However, as defined by Biology Online (http://www.biolo.qy-online.orq/dictionary/Compound), a compound is a "material made up of two or more

elements." Since a nucleotide sequence is made up of two or more elements, it is clear that a nucleotide sequence is in fact a compound.

The response further argues that it is the responsibility of the patent Office to determine if the generic claim can be allowed. This argument is not relevant to the present restriction requirement since no generic claims are currently pending.

Applicants state that they believe that the complete invention has already been searched and thereby no undue search burden is required to search the additional haplotypes. This argument is not persuasive. The claims have been searched only to the extent that they read on the elected invention of a method for diagnosing schizophrenia by assaying for the 601-1038 haplotype. The response also asserts that the search for claim 29 is the same single search that traces back to their discovery of Seq-40 in PCT/US00/31581. This argument is also not persuasive. A search for a protein named Seq-40 in PCT/US00/31581 is clearly not co-extensive with a search and examination of particular haplotypes of Seq-40 associated with schizophrenia and particularly with methods for detecting the haplotypes as indicative of a propensity for developing schizophrenia.

Applicants argue that genes can be searched by sequence, not by name, and thereby no undue burden is required to search the claimed invention. This argument has also been fully considered but is not persuasive. First, it is noted that the claims are not directed to the nucleic acid sequences per se, but rather to methods for diagnosing schizophrenia by detecting the presence of a combination of polymorphisms. Secondly, to merely search the claimed invention by searching the term “seq-40” would not

provide a complete search. A complete search for the present invention requires both a search of sequence databases and literature databases. A complete search for the elected invention requires a search for alternative alleles of this sequence, wherein there is a variation at each of the recited polymorphisms. As such a search for the polymorphisms 601 and 1038 is a distinct sequence search from a search of, for example, the polymorphisms at positions 194 and 2106. Further, many genes have more than one name and the number of polymorphisms within the gene must be individually searched for novelty. In the present situation, given the multitude of names that have been assigned to the "Seq-40" gene (i.e., TA4, TRAR4, TAAR6, etc), a search for haplotypes of this genes also requires an extensive keyword search for each of the individual haplotypes. Additionally, an article which teaches polymorphisms within a gene does not necessarily use the same numbering system or the same nomenclature as that used by Applicant or other authors. Also, many published references disclose polymorphisms within tables and figures, and this information is frequently not indexed in sequence databases or even with the abstracts of papers. An additional search burden is required to analyze the contents of tables and figures in order to determine if a polymorphism within a gene is novel or unobvious over the prior art. Therefore, it is maintained that it would require an undue burden to search and examine each of the patentably distinct haplotypes.

The responses points to MPEP 803.04 as indicating that up to 10 unrelated sequences will normally be considered together. This argument has also been fully considered but is not persuasive. With respect to claims to nucleic acids, the MPEP

states that the requirements of 37 CFR 1.141 have been partially waived to "permit a reasonable number of such nucleotide sequences to be claimed in a single application." The MPEP further states that "normally ten sequences constitute a reasonable number for examination purposes and that "up to 10 independent and distinct nucleotide sequences" (emphasis added) may be examined in a single application. Thereby, the MPEP does not in fact state that 10 nucleotide sequences will be examined in each application. Further, as set forth in the pre-OG notice of March 27, 2007 (available via url: <uspto.gov/web/offices/pac/dapp/opla/preognotice/sequence02212007.pdf>), the Office has rescinded the 1996 waiver to search up to 10 sequences due to the increasing computational, search and examination burden required for the consideration of nucleic acids sequences, and complexity of claims drawn to such, compared to the time of the 1996 waiver (see the statistics cited in the pre-OG Notice at the link above).

Accordingly, for the reasons set forth above, it is maintained that undue burden would be required to search and examine each of the claimed haplotypes together.

The requirement is still deemed proper and is therefore made FINAL.

Therefore, claims 29 and 30 have been examined herein to the extent that the claims read on the elected invention of the polymorphic sites at positions 601 and 1038. The other polymorphic sites and combinations thereof and claims 31-56 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Objections

2. Claim 29 is objected to because the claim includes subject matter of the non-elected inventions, namely the polymorphic sites other than the elected polymorphic sites at positions 601 and 1038.

Specification

3. The specification is objected to because the assigned SEQ ID NOs have not been used to identify each sequence listed, as required under 37 CFR 1.821(d). See, for example, pages 6-7 of the specification.

Claim Rejections - 35 USC § 112 second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 30 are indefinite over the recitation of "corresponds." The term "corresponds" is not an art recognized term to describe the relationship between a nucleotide and a "protein encoding sequence." It is not clear as to whether a corresponding nucleotide refers to a nucleotide is at the same position as position 601 and 1038 in SEQ ID NO: 1 or to a nucleotide at a nearby position of SEQ ID NO: 1or at the same or nearby position in a gene homologous to or otherwise similar to SEQ ID NO: 1. Because the term "corresponds" has not been clearly defined in the specification

and because there is no art recognized definition for this term as it relates to nucleic acid sequences, one of skill in the art cannot determine the meets and bounds of the claimed subject matter.

Claim Rejections - 35 USC § 112 - Enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

methods for evaluating the propensity of a human subject to develop schizophrenia comprising: i) obtaining a nucleic acid sample from a human subject, wherein the nucleic acid sample comprises a nucleic acid comprising SEQ ID NO: 1; ii) analyzing the nucleic acid to determine the identity of the nucleotides at positions 601 and 1038 of SEQ ID NO: 1; and iii) determining that said human subject has an increased propensity to develop schizophrenia if there is a G at nucleotide position 601 of SEQ ID NO: 1 and a C at nucleotide position 1038 of SEQ ID NO: 1, wherein said human subject is of Caucasian descent,

does not reasonably provide enablement for methods for evaluating the propensity of any patient to develop schizophrenia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Breadth of the Claims:

Claim 29 is drawn to a method of evaluating the propensity of a patient to develop schizophrenia comprising determining the nucleotide at a position corresponding to a Seq-40 polymorphic site at positions 601 and 1038 and evaluating whether the patient has a propensity to develop schizophrenia. Claim 30 is further limited to a method wherein it is determined that the patient has a propensity to develop schizophrenia if the identity of the nucleotide at position 601 of SEQ ID NO: 1 or a fragment thereof is a G and if the identity of a nucleotide at position 1038 of SEQ ID NO:1 or a fragment thereof is a C.

Claims 29 and 30 encompass the analysis of any patient, and thereby include the analysis of non-human subjects and human subjects of any ethnic origin.

Claim 29 further includes determining a nucleotide that "corresponds" to position 601 and 1038 of SEQ ID NO: 1. The term "corresponds" has not been defined in the specification and there is no art recognized definition for this term as it relates to nucleic acids. Accordingly, the term has been given the broadest reasonable interpretation as including nucleotides near position 601 and 1038 of SEQ ID NO: 1 and nucleic acids

sharing sequence identity with SEQ ID NO: 1 (e.g., position 600 or 590 or 1037 or 1030 of SEQ ID NO: 1 and sequences having 90% or 80% etc identity with SEQ ID NO: 1) . Further, claim 29 encompasses detecting any nucleotide – A, T, G or C, at the recited positions as indicative of a propensity to develop schizophrenia. Thereby, claim 29 is inclusive of the detection of a large genus of haplotypes as indicative of a propensity to develop schizophrenia.

Nature of the Invention

The claims are drawn to methods for evaluating a patient's propensity to develop schizophrenia by assaying for a polymorphism in a seq-40 nucleic acid. The invention is in a class of inventions which the CAFC has characterized as 'the unpredictable arts such as chemistry and biology" (Mycolgen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Federal Circuit 2001)).

Teachings in the Specification and State of the Art:

The specification (pages 6-7) teaches the sequence of a nucleic acid encoding a G-protein coupled receptor (GPCR) designated "Seq 40," wherein said nucleic acid comprises the sequence of SEQ ID NO: 1.

The specification (page 19, Table 1) further discloses 10 polymorphisms in SEQ ID NO: 1. Regarding the elected invention, the specification discloses an A to G polymorphism at position 601 and a C to G polymorphism at position 1038 of SEQ ID NO: 1.

The specification also provides the results of a study analyzing the frequency of these polymorphisms and haplotypes in a population of 309 patients having

schizophrenia. Each of the subjects analyzed were of Caucasian descent (i.e., the "parent origin" and "grandparent ethnicity" is Caucasian; see Table 3, page 46). 190 control samples were also analyzed (page 46). At page 49, the specification reports that for the 601-1038 haplotype (i.e., "S2" and "S4"), the G-C haplotype was present more frequently in the schizophrenia affected population as compared to the control population, with a p value of 0.00021. Accordingly, the specification discloses an association between risk of developing or having schizophrenia and the haplotype consisting of a G at position 601 of SEQ ID NO: 1 and a C at position 1038 of SEQ ID NO: 1 in human subjects of Caucasian descent.

The specification does not, however, teach an association between the 601G and 1038C haplotype and the occurrence of schizophrenia in human subjects of other ethnic backgrounds or in the general population. Nor does the specification teach an association between the 601G and 1038C haplotype and the occurrence of a schizophrenia phenotype in non-human subjects. Further, regarding claim 29, the specification does not teach a representative number of additional polymorphisms near position 601 and 1038 of SEQ ID NO: 1 or other nucleic acids that can be detected as indicative of a propensity to develop schizophrenia.

The Predictability or Unpredictability of the Art :

The art of determining an association between a haplotype and a disease is highly unpredictable. Knowledge that a haplotype is associated with a disease in one ethnic group does not allow one to conclude that the same haplotype is associated with a disease in other ethnic groups or in the population as a whole.

The teachings in parent application 10/230,007 (Kaytes et al, PGPUB No. 20030170667) support the unpredictability of extrapolating the results obtained from Caucasian subjects to subjects of other ethnic backgrounds. Therein the results of a study are provided in which the frequency of the haplotype comprising positions 601 and 1038 was determined in 225 individuals in which 53 individuals had an unknown maternal ethnicity, 68 individual's mother's were African American, 51 were West European, 14 were Mediterranean and 23 with other ethnic backgrounds (page 50). It was determined that the presently claimed 601G / 1038C haplotype was NOT associated with increased propensity to develop schizophrenia in the study population (p value = 0.68384; Table 5). In this study group, only the presence of the 601A / 1038C haplotype was found to be associated with a propensity to have or develop schizophrenia (p value = 0.000906; Table 5). The present specification does not provide any information regarding the frequency of the 601-1038 A-C, G-G or A-G haplotypes in subjects having schizophrenia or in control subjects.

The teachings in the prior art also support the unpredictability of extrapolating the results obtained in subjects of Caucasian descent to other ethnic groups. In particular, Ikeda (Schizophrenia Research. 2005. 78: 127-130) analyzed the occurrence of TRAR4 (i.e., SEQ ID NO: 1) polymorphisms in Japanese patients having schizophrenia. The reference reports that while one marker showed a significant associated with schizophrenia in a first study, the significance was not found in a second-set analysis. Ikeda (abstract) concludes that "Our results indicate that TRAR4 may not play a major role in Japanese schizophrenia patients, and that it is important to examine the

possibility of false positives in genetic association studies." Duan (Journal of Neural Transmission. 2006. 113: 381-385) also studied the frequency of occurrence of 3 polymorphisms in the TRAR4 gene in schizophrenia patients in a Chinese Han population, wherein the 3 polymorphisms were previously reported to be associated with the occurrence of schizophrenia. Duan did not observe a preferential transmission of any of the TRAR4 polymorphisms in schizophrenia patients (see page 385). Duan (see abstract) concluded that the "TRAR4 is not a major independent determinant of schizophrenia in the Chinese Han population." Amann (Molecular Psychiatry. 2006. 11:119-121) genotyped subjects of Arab Israeli origin for the presence of 15 SNPs in the vicinity of the TRAR4 gene, including the SNP rs6907909, which is identical to the present SNP at nucleotide position 601 of SEQ ID NO: 1 (see Table 1 and page 120). Amann did not observe an association between any of the individual SNPs and schizophrenia (page 120). Further, haplotype analysis of the SNPs together with the rs6912930 SNP did not show a significant association with schizophrenia (page 120).

The general unpredictability of establishing a correlation between a polymorphism or a haplotype and a disease is also supported by the teachings of Hirschhorn et al. (Genetics in Medicine. 2002. 4(2): 45-61). This reference teaches that most reported associations between genetic variants and diseases are not robust. Hirschhorn states that "of the 166 putative associations studied three or more times, only 6 have been consistently replicated" (see abstract). The reference sets forth a number of reasons for the irreproducibility of these studies, suggesting that population stratification, linkage disequilibrium, gene-gene or gene-environment interactions, and

weak genetic effects and lack of power are possible factors that lead to such irreproducibility. Hirschhorn concludes that "the current irreproducibility of most studies should raise a loud cautionary alarm" (page 60, col. 2). Thus, Hirschhorn cautions in drawing conclusions from a single report of an association between a genetic variant and disease susceptibility.

Moreover, the claims encompass evaluating the propensity to develop schizophrenia in any non-human subject. However, the specification does teach the occurrence of seq-40 (SEQ ID NO: 1) or polymorphisms at position 601 and 1038 of this gene in a representative number of non-human subjects. Without extensive information regarding the structure-function relationship between the haplotype and schizophrenia and in the absence of information regarding the presence of the gene and haplotype in non-human subjects, it is highly unpredictable as to whether the 601G-1038C haplotype or another 601-1038 haplotype will occur in a representative number of non-human subjects and will be associated with a schizophrenia phenotype.

Amount of Direction or Guidance Provided by the Specification and Degree of Experimentation:

Regarding claim 29, the specification does not provide sufficient guidance as to how to detect additional polymorphisms in Seq-40 or in nucleic acids having sequence identity thereto. Extensive experimentation would be required to identify additional polymorphisms associated with schizophrenia. For example, such experimentation may involve sequencing the seq-40 gene of Caucasian subjects having schizophrenia to try to identify novel polymorphisms near positions 601 and 1038, sequencing the seq-40

gene of Caucasian subjects that do not have schizophrenia to determine the frequency of novel polymorphisms near positions 601 and 1038, comparing the frequency of any polymorphisms that are present in the individuals having schizophrenia and not present in individuals that do not have schizophrenia, and performing a statistical analysis to determine whether there is a statistically significant increase or decrease in the occurrence of a novel polymorphism in individuals having schizophrenia as compared to individuals that do not have schizophrenia. Further experimentation may also include performing the above method in a representative number of human subjects different ethnic origins, such as subjects of Japanese, Chinese, European and African American descent. Additionally, the experimentation may include performing the above methods in a representative number of non-human subjects, such as cats, dog, sheep, horses etc. The experimentation may also include applying the above method to the analysis of genes that share sequence identity with seq-40, such as other genes encoding other G-protein coupled receptors. The outcome of such experimentation cannot be predicted and is thus considered to be undue.

While methods for sequencing nucleic acids are known in the art, such methods provide only the general guidelines that allow researchers to randomly search for polymorphisms that may linked to a particular phenotype. The results of performing such methodology are highly unpredictable. The specification has provided only an invitation to experiment. The specification does not provide a predictable means for identifying additional polymorphisms associated with the occurrence of schizophrenia in human or non-human subjects.

Working Examples:

The present specification provides a working example in which it was determined that the 601G-1038C haplotype occurred at a higher frequency in Caucasian subjects having schizophrenia as compared to control subjects.

No working examples are provided wherein the presence of other 601-1038 haplotypes were detected in Caucasian subjects as indicative of an increased propensity to develop schizophrenia.

No working examples are provided wherein the presence of the 601G-1038C haplotype is detected in human subjects of non-Caucasian origin as indicative of a propensity to develop schizophrenia.

No working examples are provided wherein the presence of other polymorphisms near the 601 or 1038 polymorphisms are detected in SEQ ID NO: 1 or in related nucleic acids as indicative of a propensity to develop schizophrenia.

No working examples are provided wherein non-human subject's are analyzed for the presence of a 601-1038 haplotype in order to evaluate a propensity for the subject to develop a schizophrenia phenotype.

Conclusions:

Case law has established that '(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that '(t)he scope of the claims must bear a reasonable correlation to the scope of enablement

provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that '(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement".

In the instant case, the claims do not bear a reasonable correlation to the scope of enablement because the specification only an association between Caucasian subjects having the 601G-1038C haplotype and the occurrence of schizophrenia. The specification does not teach an association between the 601-1038 haplotype and schizophrenia in a representative number of human subjects of other ethnic backgrounds or in a representative number of non-human subjects. Also, the specification does not teach an association between schizophrenia and a representative number of additional polymorphisms “corresponding” to (i.e., near or similar to) the 601-1038 haplotype in SEQ ID NO: 1 or genes showing sequence identity thereto. Accordingly, although the level of skill in the art of molecular biology is high, given the lack of disclosure in the specification and in the prior art and the unpredictability of the art, it would require undue experimentation for one of skill in the art to make and use the invention as broadly claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634